

Serial No.: 09/746,872

Please also **AMEND** the paragraph at lines 15-26 on page 61 of the Specification as filed by substituting the paragraph provided below:

A2  
Two experiments were conducted for each composition and the number of replicates is indicated in parentheses. The asterisks ("\*") in Table 3. indicate compositions having a significant difference from a water + protease insult using the Student's t-test,  $p < 0.05$ . These results were also subjected to the statistical outlier test. The results of Table 3. show that cationic decoupling polymers as well as anionic decoupling polymers have efficacy for reducing the irritation response of the skin when skin is exposed to a fecal protease insult. Both anionic and cationic decoupling polymers have a protective effect when the skin model is exposed to protease-induced irritation. AP-2 did not show activity but it is believed that AP-2 would show activity if provided in a formula that would not interfere with its negative surface charges. EPIDERM skin culture studies were conducted to measure irritation in response to a bile acid insult. The results are provided in Table 4. below.

---

#### Remarks

In the Office Action mailed March 18, 2002, claims 1-57 are pending in the application. Claims 8-9, 35-36, 42, 44 and 48 are withdrawn from consideration. Claims 1-7, 10-34, 37-41, 43, 45-47 and 49-57 are rejected.

#### 1. Election of Species

In the Office Action mailed March 18, 2002, the Examiner states that the Applicants are required under 35 U.S.C. §121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner believes that, as currently presented, claims 1-7, 10-17, 20-34, 38-41, 45-47 and 49-57 are generic. Applicants affirm their previous election of claims 18, 19, 37 and 43.

#### 2. Rejection of Claims as Obvious Over Krzysik in View of Klofta and Beerse

In the Office Action mailed March 18, 2002, the Examiner rejects claims 1-7, 10-34, 37-41, 43, 45-47 and 49-57 as being unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 6,149,934 issued to Krzysik et al. (hereinafter "the Krzysik patent") in view of U.S. Patent No. 6,238,682 issued to Klofta et al. (hereinafter "the Klofta patent") and in view of U.S. Patent No. 6,294,186 to Beerse et al. (hereinafter "the Beerse patent"). A *prima facie* case of obviousness has not been established and therefore, Applicants respectfully traverse the rejection.

Serial No.: 09/746,872

With respect to claims 1, 2, 14, 15, 20-25, 32, 39-41, 51 and 53-57, the Examiner believes the Krzysik patent discloses an absorbent article including a topsheet, a backsheet and an absorbent core located in between the topsheet and the backsheet. The Examiner believes the Krzysik patent discloses a lotion composition on the topsheet where the lotion composition is melted, applied to the topsheet and then cooled. The Examiner also believes that the Krzysik patent discloses a lotion composition having a melting temperature of between 10 and 100 degrees Celsius; a low shear viscosity between 50,000 and 80,000 centipoise; a high shear viscosity between 150 and 200 centipoise; a penetration hardness between 5 and 360 mm; and disposition on the topsheet in an amount of 1-50 grams per square meter. The Examiner acknowledges that the Krzysik patent does not disclose a lotion composition including a hydrophilic solvent, a high molecular weight polyethylene glycol, a fatty acid, a fatty alcohol and a decoupling polymer.

The Examiner believes the Klofta patent discloses a lotion composition having 5-60% hydrophilic solvent, a high molecular weight polyethylene glycol and 0.1-60% of a skin conditioning agent (such as fatty alcohols and fatty acids). The Examiner believes it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the composition of the Krzysik patent to be the composition of the Klofta patent in order to provide a lotion composition that kills viruses and imparts a soft lubricious feel. However, the Examiner acknowledges that the Krzysik and Klofta patents fail to disclose the use of a decoupling polymer and a sterol. The Examiner believes the Beerse patent discloses the use of a lotion composition that can be used on diapers and that contains about 0.1 to 10% of a decoupling polymer such as polysaccharides or polyacrylamides and that contains a skin moisturizer such as cholesterol present from 0.1 to 20%. The Examiner believes it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composition of the Klofta patent to include the decoupling agent and sterol of the Beerse patent in order to thicken the skin care composition to improve the moisturizing effect of the composition.

With respect to dependent claims 3, 26 and 45 (selection of hydrophilic solvents), the Examiner refers the Applicants to col. 17, lines 13-42 of the Klofta patent. With respect to dependent claims 4, 5, 27, 28 and 46 (molecular weight of polyethylene glycol), the Examiner refers the Applicants to col. 17, lines 23-35 of the Klofta patent. With respect to claims 6, 29 and 47 (selection of fatty alcohol), the Examiner refers the Applicants to col. 24, lines 11-14 of the Klofta patent. With respect to claims 7 and 34 (selection of decoupling polymer), the Examiner refers the Applicants to col. 16, lines 31-42 of the Klofta patent. With respect to claims 10, 11, 30 and 49 (inclusion of an emulsifying surfactant and its selection), the Examiner believes the Klofta patent discloses the use of a surfactant with an HLB value of greater than 7. The Examiner acknowledges that the Klofta patent fails to disclose the use of glycerol stearate, polysorbate or water dispersible metal salts. The Examiner believes it would have

Serial No.: 09/746,872

been an obvious matter of design choice to have the surfactant be either stearate, polysorbate or a water dispersible metal salt.

With respect to claims 12, 13, 31 and 50 (inclusion and selection of natural fats and oils), the Examiner refers the Applicants to col. 27, lines 30-37 of the Klofta patent. With respect to claims 16, 17, 33 and 52 (inclusion and selection of emollient), the Examiner refers the Applicants to col. 18, lines 10-12 of the Klofta patent. With respect to claims 18, 19, 37, 38 and 53 (inclusion and selection of a rheology modifier), the Examiner refers the Applicants to col. 24, lines 30-40 of the Klofta patent. With respect to claim 43 (application by slot coating), the Examiner refers the Applicants to col. 13, line 59 of the Krzysik patent.

Claim 1 of the present invention is directed to an absorbent article including an outer cover, a liquid permeable bodyside liner and an absorbent body that is located between the bodyside liner and the outer cover. The bodyside liner defines a bodyfacing surface and is connected in superposed relation to the outer cover. The article includes a composition on at least a portion of the bodyfacing surface of the bodyside liner. The composition includes from about 10 to about 90 weight percent of a hydrophilic solvent; from about 10 to about 90 percent by weight of a high molecular weight polyethylene glycol; from about 0 to about 40 percent by weight of a C<sub>14</sub> to C<sub>30</sub> fatty alcohol; from about 0 to about 40 percent by weight of a C<sub>14</sub> to C<sub>30</sub> fatty acid; and from about 0.1 to about 20 percent by weight of decoupling polymer. Claim 20 of the present invention is similar to claim 1 and further includes that the decoupling polymer may be selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures of such compounds.

Claim 21 of the present invention is also similar to claim 1 except the composition includes from about 10 to about 80 percent by weight of hydrophilic solvent; from about 1 to about 30 percent by weight of a C<sub>14</sub> to C<sub>30</sub> fatty alcohol; from about 1 to about 30 percent by weight of a C<sub>14</sub> to C<sub>30</sub> fatty acid; from about 1 to about 10 percent by weight of emulsifying surfactant having a combined HLB in a range greater than 7; from about 0.1 to about 30 percent by weight of natural fats or oils; from about 0.1 to about 10 percent by weight of sterols or sterol derivatives; and from about 0.1 to about 10 percent by weight of emollient (same amounts of high molecular weight polyethylene glycol and decoupling polymer). Claim 39 of the present invention is similar to claim 21 except the composition includes from about 10 to about 90 percent by weight of hydrophilic solvent and the decoupling polymer may be selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl

Serial No.: 09/746,872

alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures of such compounds.

Claim 40 of the present invention is directed to a method of applying a composition to a bodyfacing surface of a bodyside liner of an absorbent article. The method includes a step of heating a composition including a hydrophilic solvent, a high molecular weight polyethylene glycol, a C<sub>14</sub> to C<sub>30</sub> fatty alcohol, a C<sub>14</sub> to C<sub>30</sub> fatty acid and from about 0.1 to about 20 percent by weight of decoupling polymer. The decoupling polymer may be selected from homopolymers of acrylic acid, acrylic acid/maleic acid copolymers, poly(2-hydroxyethylacrylate), polysaccharides, cellulose ethers, polyglycerols, polyacrylamides, polyvinyl alcohol/polyvinyl ether copolymers, poly(sodium vinyl sulfonate), poly(2-sulphato ethyl methacrylate), poly(acrylamidomethyl propane sulphonate) and mixtures of such compounds. The composition is heated to a temperature above the melting point of the composition where the composition has a melting point of from about 32°C to about 100°C. The method includes a step of applying the composition to a bodyfacing surface of a bodyside liner of an absorbent article and a step of resolidifying the composition.

Claim 54 of the present invention is directed to a method for protecting the skin barrier on a skin surface of a user. The method includes a step of contacting the skin surface of the user with a bodyfacing surface of a liner material where the bodyfacing surface has a composition including a hydrophilic solvent, a high molecular weight polyethylene glycol, a C<sub>14</sub> to C<sub>30</sub> fatty alcohol, a C<sub>14</sub> to C<sub>30</sub> fatty acid and a decoupling polymer. The method also includes a step of maintaining the bodyfacing surface in contact with the skin surface for a sufficient amount of time to transfer the composition to the skin surface and a step of repeating the contact for a sufficient period of time to protect the skin barrier. The composition includes from about 10 to about 90 weight percent of a hydrophilic solvent; from about 10 to about 90 percent by weight of a high molecular weight polyethylene glycol; from about 1 to about 40 percent by weight of a C<sub>14</sub> to C<sub>30</sub> fatty alcohol; from about 1 to about 40 percent by weight of a C<sub>14</sub> to C<sub>30</sub> fatty acid; and from about 0.1 to about 20 percent by weight of decoupling polymer.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143. The Examiner has not identified why one of ordinary skill in the art would have been motivated to combine the disclosures of the Krzysik, Klofta and Beerse patents. The Examiner states she believes it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the composition of the Krzysik patent to be the composition of the Klofta patent and to include components of the Beerse patent in the composition of the Klofta patent, but she does not identify any specific

Serial No.: 09/746,872

disclosure of the references that would lead to such a combination. The motivation to modify the prior art must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention.

The Krzysik patent relates to absorbent articles that include a lotionized bodyside liner for improved skin health benefits. (See Col. 1, lines 7-12). Conversely, the Klofta patent relates to antimicrobial lotion compositions that are applied to tissue papers for the purpose of killing certain strains of viruses and bacteria. (See Col. 1, lines 17-29). The Examiner does not explain why one of skill in the art would have been motivated to combine the absorbent articles of the Krzysik patent with the tissue papers of the Klofta patent or why it would be desirable to modify the composition of the Krzysik patent to be the composition of the Klofta patent. In fact, it may be highly undesirable to use an antiviral/antibacterial composition to improve the skin health of wearers of absorbent articles because such compositions could kill naturally-occurring beneficial flora that protect the skin. If a proposal for modifying the prior art in an effort to attain the claimed invention causes the art to become inoperable or destroys its intended function, then the requisite motivation to make the modification would not have existed.

The Beerse patent relates to antimicrobial compositions that provide immediate as well as residual anti-viral and antibacterial efficacy. (See Col. 1, lines 44-46). The Examiner does not explain why one of skill in the art would have been motivated to include the "thickening agents" of the Beerse patent in the lotion compositions of the Klofta patent- particularly in view of the large number of groups of compounds disclosed in the Beerse patent. Additionally, no suggestion or motivation is identified for picking elements from the Beerse and Klofta patents to arrive at a composition that reduces the irritation response of skin to the enzymes in biological fluids as occurs with the compositions claimed by the present invention. The requisite motivation cannot be derived from the Applicant's specification. Further, the antimicrobial compositions of the Beerse patent have the same difficulty as those of the Klofta patent with respect to their potentially deleterious effect on naturally-occurring protective flora.

With respect to the second element of a *prima facie* case of obviousness, the combination of the Krzysik, Klofta and Beerse patents does not provide the required expectation of succeeding at the endeavor of the present invention to improve the barrier function of the skin, particularly in view of the potentially deleterious effect of antimicrobial compositions on the skin. Additionally, none of the cited references recognize the "result-effective" capability of the decoupling polymers of the present invention.

With respect to the third element of a *prima facie* case of obviousness, the combination of the Krzysik, Klofta and Beerse patents does not disclose or suggest each element of the presently claimed invention. With respect to claims 2, 23, 41 and 56, the Examiner believes the Krzysik patent discloses a lotion formulation having a low shear viscosity between 50,000 and 80,000 centipoise and a high

Serial No.: 09/746,872

shear viscosity between 150 and 200 centipoise. While the Krzysik patent discloses lotion formulations having ranges of viscosities (see Col. 12, lines 41-59), the Krzysik patent does not teach or suggest the claimed viscosity ranges under low shear or high shear conditions. Second, with respect to claim 54, the combination of the Krzysik, Klofta and Beerse patents does not disclose a method for protecting the skin barrier on a skin surface of a user (using the claimed composition) that includes a step of maintaining the bodyfacing surface in contact with the skin surface for a sufficient amount of time to transfer the composition to the skin surface and a step of repeating the contact for a sufficient period of time to protect the skin barrier. For at least these reasons, the Applicants submit that claims 1-7, 10-34, 37-41, 43, 45-47 and 49-57 are patentable over the Krzysik patent in view of the Klofta and Beerse patents.

In conclusion, and in view of the remarks set forth above, Applicants respectfully submit that the application and the claims are in condition for allowance and respectfully request favorable consideration and the timely allowance of pending claims 1-7, 10-34, 37-41, 43, 45-47 and 49-57. If any additional information is required, the Examiner is invited to contact the undersigned at (920) 721-2433.

The Commissioner is hereby authorized to charge any prosecutorial fees (or credit any overpayment) associated with this communication to Kimberly-Clark Worldwide, Inc. deposit account number 11-0875. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such extension is requested and should also be charged to our Deposit Account.

Respectfully submitted,

DAVID J. TYRRELL ET AL.

By: Alyssa A. Dudkowski  
Alyssa A. Dudkowski  
Registration No.: 40,596

CERTIFICATE OF FACSIMILE

I, Barbara D. Miller, hereby certify that on July 2, 2002, this Amendment A is being sent via facsimile to the United States Patent & Trademark Office to RightFax Number 703-872-9302.

By: Barbara D. Miller  
Barbara D. Miller